REMARKS

Claim 24 is the only claim that remains in the application. Claim 24 has been amended to clarify that the T cell response is specific to influenza. Support for this amendment can be found in paragraph [0068] as well as in Examples 2-4 showing that the T cell response is specific to influenza in immunized mice. The term "vaccine agent" has also been defined according to paragraph [0051]. No new matter has been added.

Claim 24 stands rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,614,504 to Hadden, et al. Specifically, the Office Action holds that Hadden, et al. discloses a method of enhancing the immune response to a vaccine comprising administering an adjuvant formulation comprising inosine 5'-monophosphate compounds, including MIMP, administering the IMP compounds to treat influenza, measuring a response to the vaccine, and measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds. In response to previous arguments, the Office Action holds that squalene is used in vaccines as part of an adjuvant formulation and can be considered a "vaccine agent" as recited in the instant claims, and also that the claims are not limited to detecting an influenza specific T cell response. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Hadden, et al, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Hadden, et al. does not disclose the combination of an IMP with an agent chosen from the group consisting of antiviral agents, microbial agents, vaccine agents, wherein the vaccine agent can be ineffective alone in inducing a therapeutic clinical response, and combinations thereof, in order to treat influenza. Example 10 in Hadden, et al. shows that mice challenged with influenza virus were administered MIMP or Squalene, which is merely an excipient in formulation, plus MIMP. Hadden, et al. only discloses administering the IMP compound itself in treating various conditions, including influenza.

In contradistinction, the present invention requires the presence of an agent. The agent enhances the effect that the IMP compound has on the influenza as compared to administering the IMP compound alone. Applicants note that squalene as defined in the present application is an adjuvant, but not a vaccine agent (see paragraph [0054]). A vaccine agent refers to proteins, peptides, coat proteins, viral coats, viruses, bacteria, antigen, whole cells, cell components, parasites, pathogens, and any other vaccine agent known to those of skill in the art, as described in paragraph [0051]. Thus, a vaccine agent does not encompass squalene. To further clarify this, claim 24 has been amended to further define the term "vaccine agent" as in paragraph [0054].

Furthermore, while Hadden, et al. describes a general T cell stimulation when IMP compounds are applied to cells, such as in Example 2 and Example 3, ***Hadden, et al. does not show a T cell response specific to influenza*** but rather only that mice given MIMP increased mean survival time in Example 10. Therefore, Hadden, et al. cannot perform the step of detecting a T cell response specific to influenza with respect to a treatment for influenza. One cannot assume that a T cell response is present in an unhealthy subject that cannot mount an immune response normally just because a T cell response has been observed in healthy, normal cells.

The present invention shows a T cell response for the first time in influenza challenged mice, as shown in Examples 2-4. Claim 24 has also been amended to state

that the T cell response detected is specific to influenza. Without having shown that IMP provides a T cell response specifically to influenza, Hadden, et al. cannot disclose the method of the present invention.

Therefore, since Hadden, et al. does not disclose IMP in combination with an agent or detecting a T cell response in influenza as set forth in the presently pending independent claims, the claims are patentable over Hadden, et al. and reconsideration of the rejection is respectfully requested.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. Claims have also been amended to clearly distinguish over the prior art. The application is made at least in better condition for appeal as the amendment removes many issues thereby simplifying the issues on appeal. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

/Kenneth I. Kohn/
Kenneth I. Kohn, Reg. No. 30,955
Customer No.: 48924

Dated: September 23, 2010

CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

Date of Electronic Filing: September 23, 2010

I hereby certify that this correspondence is being electronically filed with the United States Patent & Trademark Office on the above date.

/Sherry Kelly/
Sherry Kelly